PUBLIC, REDACTED VERSION

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,	)	
	)	
Plaintiff,	)	Case No. 1:21-cv-10656-JGK
	)	
v.	)	**PUBLIC, REDACTED VERSION**
	)	
CORERX, INC.,	)	
	)	
Defendant.	)	
	)	
	)	

DECLARATION OF AMIT M. PATEL IN SUPPORT OF AZURITY PHARMACEUTICALS, INC.'S MOTION TO INTERVENE TO MOVE FOR RECONSIDERATION OF OR APPEAL ORDER GRANTING INJUNCTIVE RELIEF

I, Amit M. Patel, declare as follows:

1. I am currently the Chairman and Chief Executive Officer ("CEO") for Azurity Pharmaceuticals, Inc. ("Azurity"). Silvergate Pharmaceuticals, Inc. ("Silvergate") is wholly owned by Azurity. I refer to both collectively as "Azurity" in my declaration. My responsibilities include overseeing Azurity's development, operational, commercial, and corporate functions, and guiding product strategy for the company's portfolio (including Epaned®).

2. I have been the CEO of Azurity since January 2020. I have been a member of the Board of Directors of Azurity since 2018.

3. I have over twenty years of healthcare industry experience, including as Senior Vice President ("SVP") and President of Dosage Form Solutions at Capsugel, a company that provided products and services to pharmaceutical and nutritional companies, and as Executive Vice President and Head, North America, and SVP and Head, Global Corporate Development & Strategic Planning, at Dr. Reddy's Laboratories, Inc., a publicly-traded, global specialty-generic pharmaceutical company.

4. In my role as CEO for Azurity, I am familiar with, among other things, the marketing, brand development, sales, pricing, and customer interface aspects of Epaned®, as well as Azurity's other products. I am also familiar with Azurity's product portfolio, including the interrelated aspects of its cardiovascular portfolio, Azurity's research and development strategy, financial performance, and plans for capital investments. I am also familiar with efforts Azurity has invested in educating and fostering relationships with customers, such as pediatric cardiologists.

5. I provide the facts set forth in this declaration based on my personal knowledge and, if called as a witness, I would be able to testify to those facts.

I. AZURITY AND EPANED®

6. Azurity is a specialty pharmaceutical drug company focused on developing medication for underserved populations, namely pediatric and elderly patients. Azurity presently has approximately six FDA-approved products on the market, with approximately [redacted] In both 2020 and 2021, Azurity's total net revenues were less than [redacted]

7. Azurity's Epaned® is an easy-to-swallow, enalapril liquid medication indicated for the treatment of hypertension, heart failure, and left ventricular dysfunction ("LVD") that is especially well-suited for pediatric and elderly patients. Epaned® has been a brand and product many years in the making. Following nearly a decade of research and development, which cost multiple millions of dollars, Epaned® represents Azurity's unique solution to the decades-old "pill burden" associated with oral administration of solid enalapril tablets as well as the patient safety concerns that arise from compounding such oral tablets into solution. In fact, it was the first FDA-approved ready-to-use enalapril solution.

8. Epaned® was the first cardiovascular product and accounted for approximately [redacted] making it our [redacted] product by revenue. In 2021, despite facing a generic challenge, Epaned® remained an important product. In particular, it accounted for approximately [redacted] of Azurity's 2021 net revenue. Epaned®'s 2021 revenue share was initially similar to that for 2020, until generic challenge resulted in Epaned® dropping to about [redacted] of net revenue. Nonetheless, Epaned® remains our [redacted] product by revenue for 2021.

9. Azurity owns several patents directed to stable oral liquid formulations of enalapril. These include U.S. Patent Nos. 9,669,008, 9,808,442, 10,039,745, 10,154,987, 10,772,868, 10,786,482, 10,799,476, 10,918,621, 11,040,023, 11,141,405, and 11,173,141.

II. BIONPHARMA'S ABBREVIATED NEW DRUG APPLICATION & CORERX

10. Bionpharma Inc. ("Bionpharma") filed an Abbreviated New Drug Application ("ANDA") No. 212408, which is for a generic enalapril oral solution product to Azurity's Epaned®. While Bionpharma's ANDA was pending at FDA, Azurity sued Bionpharma for patent infringement by its generic drug product of several of the patents I identified above. Later, after additional patents issued, Azurity brought additional suits for Bionpharma's infringement of the newly obtained patents. Litigation concerning Bionpharma's infringement is ongoing.

11. Following Bionpharma's sale of its ANDA product that was manufactured and supplied by CoreRx Inc. ("CoreRx"), Azurity sued CoreRx for patent infringement based on that manufacture and supply. Azurity sued CoreRx where it is located (M.D. Fla.) and where the rest of the dispute was already being litigated (D. Delaware). Azurity and CoreRx were able to negotiate a settlement between the parties for CoreRx's infringement and entered into a Litigation Settlement Agreement on November 24, 2021. Ex.[1] 7. In the agreement, the parties agreed to

[1] Ex. refers to Exhibits in the Eli B. Richlin Declaration accompany this Declaration.

mutually dismiss the CoreRx actions, CoreRx agreed to cease its infringement (i.e., cease manufacturing and selling the generic drug product), and the parties agreed to certain limited releases. *Id.* Importantly, Azurity's release was expressly conditioned upon CoreRx not resuming its infringing manufacturing and supply activities because Azurity retained the right to sue CoreRx should it resume infringement and the right to seek damages for CoreRx's past infringement which would otherwise be released so long as CoreRx did not resume any infringement. *Id.* Should CoreRx breach its promise to cease its infringement and if CoreRx resumes manufacturing and supplying Bionpharma with any generic drug product (even a small number of bottles), Azurity fully intends to exercise its rights under the Litigation Settlement Agreement to not only sue for the new infringement but also to seek damages for all of the past infringement the parties had otherwise settled.

12. I understand that Bionpharma has speculated that NovaQuest Capital Management L.L.C. ("Novaquest") participated in a strategy relating to Azurity's litigations against CoreRx and the settlement thereof. That is not true. Novaquest was not involved in Azurity's decision to initiate litigation against CoreRx and took no positions on whether the companies pursued or reached settlement. Moreover, Bionpharma has speculated that CoreRx and Azurity are somehow working in collusion to protect one-another's interests. This is absolutely false – both parties are only looking towards their own interests.

13. At this time, Azurity has not yet fully calculated its damages due to CoreRx's infringement prior to the date of the CoreRx Litigation Settlement Agreement. Neither Bionpharma nor CoreRx have provided their sales records to-date and thus Azurity does not know how many bottles of infringing generic drug product CoreRx manufactured and supplied to Bionpharma, and how many bottles Bionpharma sold to pharmacies. However, using data that

can be purchased from a third-party aggregator, it appears that from Bionpharma's launch through the week of January 14, 2022, at least 14,233 units of Bionpharma's infringing generic drug product were sold by pharmacies. Ex. 14. Using only an estimate of Azurity's gross per unit profit over this period, approximately [redacted] per unit, Azurity's rough estimate is that it has lost profits of more than [redacted] Again, this is an estimate without the benefit of any actual production or sales information from Bionpharma and this does not account for units that may have been sold by Bionpharma to pharmacies but have not yet been sold by such pharmacies. Thus this underestimates Azurity's damages from CoreRx's past manufacturing and supply and Bionpharma's infringing sales of such supply.

14. I understand that Bionpharma has asked this Court to order CoreRx to manufacture and supply 18,000 units for Bionpharma. First, I note that 18,000 units is ***more*** than the number of units of Bionpharma product sold to-date. Thus, this is not a small volume given this context and it would enable Bionpharma to continue its infringement for more than the time period it has already been infringing through its commercial sales activities (since August 2021). Second, should CoreRx be ordered to resume its infringement (i.e., manufacture and supply the generic drug product) for these 18,000 bottles, I estimate that Azurity would lose profits of an additional minimum of [redacted] on such sales, again using my estimate of Azurity's gross per unit profit described above.

15. Azurity has also asserted and would continue to assert that the infringement has been willful and would continue to be, if resumed. Under applicable law, a Court is likely to multiply damages up to three-times for willful infringement. Three-times the damages amounts roughly estimated above (again without the benefit of actual numbers/data from Bionpharma and

which does not account for additional infringement if Bionpharma secures another supplier) totals more than [redacted]

III. IMPACT OF BIONPHARMA'S AT-RISK GENERIC LAUNCH

16. Bionpharma launched its generic oral solution product to Azurity's Epaned® on or about August 16, 2021. Sales of Epaned® declined beginning in August 2021. Azurity missed its overall projected revenues for the third quarter of 2021, and significantly missed its projected overall revenues for the fourth quarter of 2021 primarily due to the Epaned® decline. The decrease in the market and financial performance of Epaned® from 2020 to 2021 is due to the entrance of Bionpharma's competing generic product.

17. Because Bionpharma is no longer being supplied its generic version of enalapril maleate and barring any resumption of Bionpharma's supply or entry of another generic competitor, we would expect Epaned®'s sales to rebound, that revenues attributable to Epaned® would recover and, in certain forecasted scenarios, could potentially increase in 2022 and 2023 relative to the product's performance in 2020. However, if Bionpharma were to resume sales of its infringing generic version of Epaned®, it would likely continue to suppress Azurity's sales and depress is revenues. This would have significant negative impacts on Azurity, as set forth in further detail below.

18. Unlike large, long-established pharmaceutical companies with multiple departments and product lines, Azurity is a small, private equity-backed specialty pharmaceutical company. The profits and cashflow generated by Epaned® are not dispersed to investors, but reinvested into the company, as well as the therapeutic-area markets we actively support. Accordingly, if revenue for Epaned® continued to significantly drop due to market re-entry of Bionpharma's generic of Epaned®, the additional lost revenue would continue to directly harm

Azurity's ability to invest in its own future, and the company would have to reassess how to manage research and development efforts, personnel head count, and capital investments.

19. For example, due to Azurity's reduced revenues from Bionpharma's infringement, Azurity reduced or deferred R&D spend relative to the budget. If Bionpharma resumes its infringing sales, Azurity's expected profit would continue to decline and the company would in turn be required to implement cost savings in various areas, including R&D. A reduction in Azurity's R&D budget would impact new products that are in development, which would significantly delay the realization of future revenues from new or improved products, and has the potential to delay or even prevent some products from being brought to the market in the future. As each R&D development product is anticipated to fill an unmet need to patients who currently lack access to unique formulations that satisfy unmet patient needs, the potential harm to customers and patients is significant and immeasurable.

20. Moreover, following Bionpharma's launch of its infringing generic drug product, Azurity resisted workforce reductions, knowing that once they are implemented, rehiring lost talent would be difficult. However, Azurity was forced to institute an employee hiring freeze, other than for certain pre-approved roles. Given the importance of Epaned® to Azurity's overall economic well-being, continued erosion of Azurity's sales and revenues because of a resumption of Bionpharma sales will once again require Azurity to revisit workforce sizing.

21. Further, the brand recognition of Epaned® provides credibility and "opens the door" for other products sold by Azurity. In particular, Azurity uses Epaned® as a "foot in the door" product to promote its other cardiovascular products. If Bionpharma were to resume sales of its generic product, it would negatively impact this practice.

22. Additionally, allowing Bionpharma to resume selling its infringing generic would likely exert downward price pressure on the price of Epaned®. Indeed, in the event of Bionpharma's resumption of infringement, Azurity would be forced to launch an authorized generic ("AG") of Epaned® to mitigate loss of revenue to Bionpharma's infringing generic. Although an AG would be sold without any Epaned® branding and without the Epaned® name, at least some of the revenue from sales of the AG would flow to Azurity. By contrast, if Bionpharma were to resume its infringing sales and Azurity did not launch its own AG, then Azurity would suffer substantial loss of revenue. But even by selling an AG, Azurity would still suffer a significant loss of revenue because that AG would be sold at a fraction of the price of branded Epaned® and that AG would capture only a portion of the generic market share (i.e., generally, when an AG is priced similar to generic which would be at a fraction of the original brand price, the market share for the AG would likely be only about 50% of the generic volume). Furthermore, a portion of the any profits from the AG would need to be shared with an AG partner. These damages, when incurred, would be above and beyond the damages described in Paragraphs 14-15.

23. Nor would any of these above harms automatically be reversed should Bionpharma's generic product be taken off the market (*e.g.*, following a court order after a judgment finding Bionpharma's product to indeed be infringing). Instead, there is substantial uncertainty regarding whether and to what extent Azurity could restore Epaned® sales to their pre-generic level. In particular, it would not be an easy proposition to simply remove the AG from the market. Once launched, Azurity will likely have entered into various contracts regarding the AG (*e.g.*, with the AG manufacturer, with the AG commercial partner, with customers including wholesalers/retailers/institutions, etc.), and thus would likely not be able to immediately withdraw the AG without risking breaching any of those contracts. Accordingly, should Bionpharma resume

its infringement with its generic of Epaned®, Azurity may be subject to significant and irreversible harm.

24. Even if Azurity is able to secure a damages judgment for the infringement of its patents by Bionpharma's generic product, I have concern that Azurity would be able to collect that judgment from either Bionpharma or CoreRx. I understand that CoreRx has represented that it would be unable to pay such damages and doubts Bionpharma's ability to indemnify it for the same, and damages would be significant. This is particularly because Azurity's average gross profits for Epaned® were approximately [redacted] per month prior to Bionpharma's entry. Given that Bionpharma requested a February 2024 trial date (and the Court granted its request over Azurity's objections and desire for a speedier trial), Azurity may lose more than [redacted] in lost profits before even considering any multiplier of damages for willful infringement, which it would be unable to recover if neither CoreRx or Bionpharma could satisfy an award of this size.

25. To the contrary, Azurity has agreed to indemnify CoreRx for damages it faces from Bionpharma through the present litigation, and does have the resources to satisfy an award against CoreRx in the event that Bionpharma ultimately prevails in its claims here.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

2/2/2022
Date

Signature